

# Second-generation cryoballoon ablation for paroxysmal atrial fibrillation: 1-year follow-up

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## Background

The novel cryoballoon Advance (CB-A) has proven to achieve significantly lower temperatures and faster pulmonary vein isolation (PVI) times in comparison with the first-generation device. Although acutely very effective, to the best of our knowledge, data on mid-term clinical follow-up is lacking.

## Aims

The aim of the study was to analyse the freedom from recurrence of atrial fibrillation (AF) on a 1-year follow-up period, in a series of consecutive patients having undergone PVI with the CB-A for paroxysmal AF (PAF).

## Methods and results

Forty-two patients [30 male (71%); mean age:  $57.9 \pm 21.1$  years] were included. All patients underwent a procedure with the large 28 mm CB-A. A total 168 PVs were depicted on the pre-procedural computed tomography scan. All PVs (100%) could be isolated with the CB only. The freedom from AF off-antiarrhythmic drug treatment after a single procedure was 78% of patients at a mean  $11.6 \pm 2.0$  months follow-up. If considering a blanking period (BP) of 3 months, success rate was 83%. Phrenic nerve palsy (PNP) was the most frequent complication occurring in 19% of individuals.

## Conclusion

The CB-A is very effective in producing PVI and affords freedom from AF at 12 months follow-up in 83% of patients affected by drug-resistant PAF following a 3-month BP. The most frequent complication observed was PNP which occurred in 19% of patients. All PNP reverted during follow-up.

## Keywords

Cryoballoon • Atrial fibrillation • Pulmonary vein isolation • Mid-term outcomes

## Introduction

The second-generation version of the Cryoballoon (CB-A) (Arctic Front Advance, Medtronic) has been recently launched on the market with technical modifications designed to significantly improve procedural outcome with respect to the first-generation balloon. The number of injection ports has been doubled, from 4 to 8, and these have been positioned more distally on the catheters shaft resulting in a larger and more uniform zone of freezing on the balloons surface if compared with the previous version. In fact, the CB-A has proven to achieve significantly lower temperatures and faster isolation times in comparison with the first-generation device.<sup>1–4</sup> Although acutely very effective, to the best of our

knowledge, data on mid-term clinical follow-up are lacking. Hypothetically, the CB-A might offer a higher rate of freedom from atrial fibrillation (AF) recurrence than its predecessor due to the better acute procedural outcomes. In the present study, we analysed the clinical outcome of patients having undergone a single-procedure CB-A on a 1-year follow-up period.

## Methods

### Aim of the study

The main aim of the study was to analyse the freedom from recurrence of AF in a series of consecutive patients on a 1-year follow-up period having

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## What's new?

- Although the novel second-generation cryoballoon Advance (CB-A) has proven its acute efficacy in the setting of pulmonary vein isolation (PVI), data on mid-term follow-up is lacking in today's literature.
- In the present study, we analysed the mid-term outcomes on a 1-year follow-up period in a series of consecutive patients having undergone PVI with the CB-A for drug-resistant paroxysmal atrial fibrillation (PAF).
- Cryoballoon Advance is very effective in producing PVI and affords freedom from AF at 12 months follow-up in 83% of patients affected by drug-resistant PAF following a 3-month blanking period.

undergone pulmonary vein isolation (PVI) with the CB-A for drug-resistant PAF.

## Patient population

### Inclusion criteria

Patients having undergone CB-A for PAF were consecutively included in our analysis.

### Exclusion criteria

The exclusion criteria were any contraindication for the procedure including the presence of an intracavitary thrombus, uncontrolled heart failure, and contraindications to general anaesthesia and persistent AF.

## Pre-procedural management

All patients provided written informed consent to the ablation procedure. Structural heart disease was defined as: coronary artery disease, impaired left ventricular ejection fraction (LVEF) <40%, LV hypertrophy >15 mm, valvular insufficiency >grade 2/4, significant valvular stenosis, and prior valve replacements. A transthoracic echocardiogram (TTE) was performed within 1 week prior to ablation enabling assessment of the LVEF and intracavitary dimensions. To exclude the presence of thrombi in the left atrial (LA) appendage, all patients underwent transoesophageal echocardiography the day before the procedure. Also, patients underwent a pre-procedural computed tomography (CT) scan to assess detailed LA anatomy.

## Ablation procedure

The ablation procedure was performed as previously described.<sup>5,6</sup> Briefly, after having achieved LA access, a 100 U/kg heparin intravenous bolus was given. A 0.32 F Emerald exchange wire (Cordis, Johnson and Johnson) was advanced in the left superior PV and a steerable 15 F over-the-wire sheath (FlexCath Advance, Cryocath) was positioned in the LA. A 20 mm diameter inner lumen mapping catheter (ILMC) (Achieve, Medtronic) was then advanced in each PV ostium to obtain baseline electrical information. After withdrawing the mapping catheter, a 28 mm double-walled cryoballoon (Arctic Front Advance, Cryocath) was advanced over the ILMC up to the LA, inflated, and positioned in the PV ostium of each vein. Optimal vessel occlusion was considered to have been achieved when selective contrast injection showed total contrast retention with no backflow to the atrium. Once occlusion was documented, cryothermal energy was started. CryoApplications lasted 4 min. A bonus freeze following isolation was systematically performed

unless phrenic nerve palsy (PNP) occurred. Usually, the left superior pulmonary vein (LSPV) was treated first, followed by the left inferior (LIPV), right inferior (RIPV), and right superior pulmonary vein (RSPV). To avoid PNP the decapolar catheter was inserted in the superior vena cava, and diaphragmatic stimulation was achieved by pacing the ipsilateral phrenic nerve with a 1000 ms cycle and a 20 mA output. The reason of pacing at such a slow rate was to prevent catheter displacement, due to diaphragmatic contraction, in the early phases of application. During the whole procedure, activated clotting time was maintained over 250 s by supplementing heparin infusion as required.

## Assessment of electrical isolation

Pulmonary vein activity was recorded with the ILMC at a proximal site in the ostium prior to ablation in each vein. During ablation, if PVPs were visible during energy delivery, time to isolation was recorded when PVPs completely disappeared or were dissociated from LA activity. If PVPs were not visible during ablation due to a distal positioning of the ILMC, the latter was immediately retracted after completion of the freeze–thaw cycle to a more proximal position in which PVPs had been recorded prior to ablation. If needed, pacing from the distal or proximal CS catheter was performed to distinguish far-field atrial signals from PVP recorded on the mapping catheter, for left and right-sided veins, respectively.

## Post-ablation management

Patients were discharged the day following ablation if the clinical status was stable. After the intervention, the patients were continuously monitored with electrocardiogram (ECG) telemetry for at least 18 h. Before hospital discharge, all patients underwent TTE to exclude pericardial effusion and chest X-ray. Oral anticoagulation was started the evening of ablation and continued for at least 3 months. Antiarrhythmic drug treatment (AAD) was continued for 3 months.

## Follow-up

After the procedure, clinical evaluation and baseline ECG were planned at 1, 3, 6, 12 months. Holter monitoring lasting a minimum of 24 h were planned at 1, 3, 6, 12 months. As all patients were symptomatic before ablation, any symptoms were deemed as deserving a Holter recording or event recorder registration, unless symptom correlating arrhythmia was documented on an ECG during hospital visit. Furthermore, telephone calls with all the patients were performed at regular intervals during follow-up. All documented AF episodes of >30 s were considered as a recurrence. A blanking period (BP) of 3 months was considered for the study. All episodes of AF recurrence, including the ones occurring in the BP, were taken into consideration for final analysis.

## Statistical analysis

Data are given as mean and standard deviation or as absolute values and percentages as appropriate. Kaplan–Meier analysis was performed to describe the survival free from AF. Cox regression was performed to identify predictors of success. Statistical significance was considered if *P* value was <0.05. Statistical analyses were conducted using SPSS software (SPSS v21).

## Results

### Baseline population characteristics

Since the inception of the second-generation CB-A in our centre in June 2012, we included the first 42 patients [30 male (71%); mean age: 57.9 ± 21.1 years [having undergone consecutively PVI with

this novel tool for drug-resistant PAF. Mean time of AF was  $28.5 \pm 18.6$  months. Mean LA size was  $42.1 \pm 6.4$  mm. All patients failed  $\geq 1$  Class I or III AAD. A total of 168 veins were depicted on the pre-procedural CT scan. No patient was excluded due to anatomical reasons based on the pre-procedural CT scan. A four distinct PV pattern was present in 38 (90.4%) patients, whereas discrete left common ostium could be observed in 4 (9.6%). Table 1 shows the baseline clinical and anatomical characteristics of the study population.

## Procedural characteristics

All patients underwent a procedure with the large 28 mm CB-A. The mean total procedure and fluoroscopy times were  $95.2 \pm 16.2$  and  $20.5 \pm 12.2$  min, respectively. The mean number of freeze–thaw cycles was:  $2 \pm 0.4$  in the LSPV,  $2 \pm 0$  in the LIPV,  $1.9 \pm 0.3$  in the RSPV, and  $1.9 \pm 0.3$  in the RIPV. The mean minimal temperature achieved were:  $-54.1 \pm 6^\circ\text{C}$  in the LSPV,  $-49.5 \pm 5.2^\circ\text{C}$  in the LIPV,  $-55.6 \pm 5.5^\circ\text{C}$  in the RSPV, and  $-51.1 \pm 6.2^\circ\text{C}$  in the RIPV. In case of the occurrence of a common ostium the veins were treated separately (Table 2).

**Table 1** Baseline clinical and anatomical characteristics of the study population

Age, years (SD)	57.9 (21.1)
Male (%)	30 (71)
Duration of symptoms, months (SD)	28.5 (18.6)
Hypertension (%)	40
Diabetes (%)	11.1
Dyslipidaemia (%)	20
HF (%)	2.2
CHA <sub>2</sub> DS <sub>2</sub> VASc (SD)	1.3 (1.1)
LVEF % (SD)	58.7 (5.4)
LA dimension, mm (SD)	42.1 (6.4)
PV common ostium (%)	9.6

AF, atrial fibrillation; BMI, body mass index; HF, heart failure; LVEF, left ventricular ejection fraction; LA, left atrium; PV, pulmonary vein.

**Table 2** Procedural characteristics

Procedure time, min (SD)	95.2 (16.2)
Fluoroscopy time, min (SD)	20.5 (12.2)
LSPV number of freezes (SD)	2 (0.4)
Minimal temperature ( $^\circ\text{C}$ )	$-54.1$ (6)
LIPV number of freezes (SD)	2 (0)
Minimal temperature ( $^\circ\text{C}$ )	$-49.5$ (5.2)
RSPV number of freezes (SD)	1.9 (0.3)
Minimal temperature ( $^\circ\text{C}$ )	$-55.6$ (5.5)
RIPV number of freezes (SD)	1.9 (0.3)
Minimal temperature ( $^\circ\text{C}$ )	$-51.1$ (6.2)

LSPV, left superior pulmonary vein; LIPV, left inferior pulmonary vein; RSPV, right superior pulmonary vein; RIPV, right inferior pulmonary vein.

## Pulmonary vein isolation

All 168 PVs (100%) could be isolated with the 28 mm CB-A. Isolation could be achieved during the first freeze in 89% of LSPV, in 100% of LIPV, in 93% of RSPV, and in 84% of RIPV. Early recovery of LA–PV conduction could be observed in three PVs (2%) following the bonus freeze (two RIPVs; one RSPV). In one RSPV and one RIPV performing an additional cryoenergy application while positioning the Achieve catheter deeper in the vein led to better CB stability in the ostium. Consequently, isolation could be achieved in both the veins without further observing early LA–PV reconnection. In the remaining RIPV a pull-down manoeuvre was performed with electrical documentation of very short time to isolation.

## Real-time recordings

Real-time recordings could be observed in 52% of PVs (70% LSPV; 45% LIPV; 55% RSPV; 40% RIPV). The mean time to isolation and temperature at isolation were:  $45 \pm 25$  s and  $35 \pm 10.2^\circ\text{C}$  in the LSPV;  $33.4 \pm 8$  s and  $28.6 \pm 4^\circ\text{C}$  in the LIPV;  $31.3 \pm 12$  s and  $26 \pm 8.9^\circ\text{C}$  in the RSPV; and  $52 \pm 35$  s and  $30.0 \pm 4.2^\circ\text{C}$  in the RIPV.

## Complications

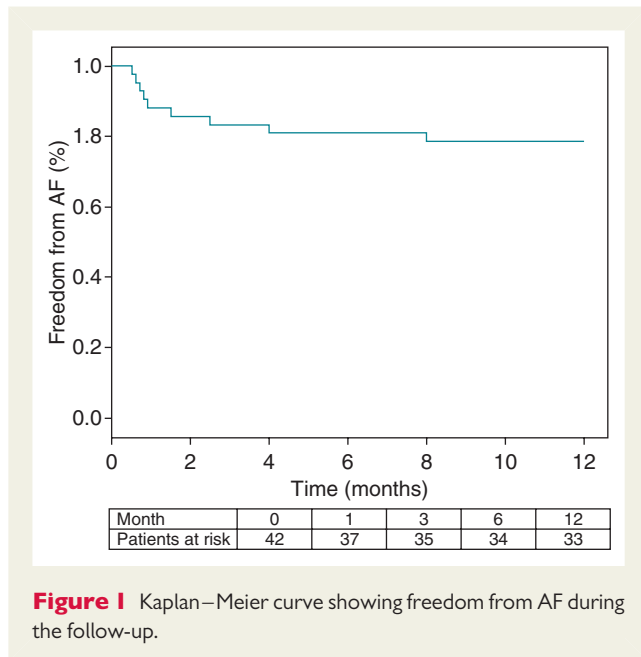
The most frequent complication observed was transient PNP which occurred in eight (19%) of the cases. Phrenic nerve palsy occurred during cryoenergy applications in three RIPV (37.5%) and in five RSPV (62.5%), respectively. In 62.5% (five out of eight), PNP resolved completely before discharge. In three cases (37.5%), this complication persisted after discharge. In two (5%) patients, the sniff test performed 2 months after the procedure showed a total recovery of the diaphragmatic function. In one patient, the recovery of PNP occurred after 10 months following ablation. At the time of PNP the PVs were all isolated. Of note, virtually all PNPs occurred in the first 20 patients (7/8). The rate of this complication was dramatically reduced in the following patients in which more proximal applications with less vigorous wedging were performed in the right-sided veins. One (2.2%) patient experienced a pseudoaneurysm which required surgical treatment.

## Follow-up

The freedom from AF off-AAD treatment after a single procedure was 78% (33 patients) at a mean  $11.6 \pm 2.3$  months follow-up. If considering a BP of 3 months, freedom from AF off-AAD treatment was achieved in 83% (35 patients). Freedom from AF was 85% at 3 months, 81% at 6 months, and 78% at 12 months after single procedure (Figure 1). No predictors of AF recurrence were found.

Four patients (9%) underwent a repeat ablation procedure which consisted in redo PVI in three (7%) and in roof-dependent LA flutter ablation in one (2.3%). At the repeat ablation procedure, a mean 1.3 PVs per patient exhibited electrical reconnection. Ablation was carried out with an open-irrigated tip radiofrequency ablation catheter. These patients did not experience arrhythmic recurrence following repeat ablation.

Three patients (7%) refused a repeat procedure because of freedom from AF with previously ineffective AAD treatment. The latter were free of AF at final follow-up.



**Figure 1** Kaplan–Meier curve showing freedom from AF during the follow-up.

## Discussion

To the best of our knowledge, this is the first study reporting 1-year outcomes after a PVI with the second-generation CB-A in patients affected by PAF. The main findings of our study are that freedom from PAF off-AADs could be achieved in 83% of patients following the BP. Other findings were that (i) all veins could be isolated with the 28 mm CB-A only, (ii) the most frequent complication is PNP, and that (iii) we could not find predictors of recurrence.

### One-year follow-up with the cryoballoon Advance

Recent articles describing long-term outcome after first-generation CB are available in the literature.<sup>7,8,9,10</sup> In 2008, Neumann *et al.*<sup>7</sup> described a 74% freedom from AF at 1-year follow-up in a large cohort of patients. However, this population consisted of patients having undergone procedures with either balloon sizes (23 or 28 mm), or even both sizes in a non-negligible amount of individuals. Similarly, in a large multicentre trial comparing outcomes with AADs to CB ablation in a randomized fashion, freedom from AF could be achieved in roughly 70% of patients.<sup>8</sup> Recently, Vogt *et al.*<sup>9</sup> published their findings on long-term follow-up after CB ablation in a large cohort of patients. In this study, nearly half of the cohort underwent a procedure with both balloon sizes. Although in Vogt's article the mean follow-up reached 2 years, when analysing freedom from AF at 1 year roughly 75% of patients did not experience arrhythmic recurrence. Interestingly, the results appeared significantly better with the smaller 23 mm balloon if compared with the bigger 28 mm diameter when a single balloon strategy was performed. In fact, the success rates following a single procedure with the 28 mm balloon were relatively deceiving. This might be explained by the fact that with the first-generation CB, due to the specific number and positioning of the jets delivering refrigerant gas, the lesion around the PV (corresponding to the coldest area on the balloon's

surface) might have been more homogeneous when using the smaller balloon size resulting in more circumferential and permanent lesions around the PV ostium. In our study, freedom from arrhythmic recurrence could be achieved in 83% of patients after the BP following a single ablation using the 28 mm CB-A. This finding is promising and the discrepancy in the outcomes might be explained by the significant technological improvements of the second-generation CB with respect to its predecessor. The number of injection ports has been doubled, from 4 to 8, and these have been positioned more distally on the catheters shaft resulting in a larger and more uniform zone of freezing on the balloons surface. In accordance, recently published animal data<sup>3,4</sup> convincingly showed that the CB-A creates wider and more homogeneous lesions around the PV antrum in comparison with the previous version. This was further confirmed by first studies in humans, which demonstrated significantly improved acute procedural outcomes with this device if compared with the first-generation balloon. These articles importantly observed a significantly higher rate of single-shot PVI. Therefore, hypothetically, these improved acute outcomes being a reflection of more optimal freezing and therefore lesion creation, might lead to a higher proportion of permanently isolated PVs.

### Single balloon procedure

To ensure full contact between the coldest freezing area of the first-generation CB and the PV ostium, the device had to be positioned coaxially to the orientation of the vessel. This proved to be a limitation of the technology given the fact that it was often difficult to position the guidewire in an optimal PV branch to achieve full occlusion. This was further complicated by the enormous anatomical variations of the PV ostia shapes and orientation encountered in patients undergoing AF ablation. Due to these limitations, most publications addressing acute procedural outcomes with the first-generation CB stated that touch-ups with an additional focal tip catheter were not seldom needed to complete PVI. In the seminal paper by Van Belle *et al.*,<sup>11</sup> an additional focal tip catheter was needed to isolate up to 16% of PVs. Similarly, Neumann *et al.*, reported that 11% of PVs needed focal 'touch-up' to be electrically isolated. Furthermore, as mentioned previously, some authors have suggested the use of both balloon sizes in the same patient to better tackle these anatomical variations in size.<sup>9,12</sup> Conversely, Chun *et al.*<sup>13</sup> described their own positive experience with the use of the sole large diameter CB. However, it should be underlined that the study population was small and that the interesting alternative techniques proposed in case of failure to occlude (such as the pull-down, hockey stick, or big-loop manoeuvre) might not be reproducible in all anatomical variants. In our study, all veins could be isolated with the single large diameter CB-A. As mentioned in the section above, the wider and more uniform freezing area might minimize the need of having to position the CB-A in a coaxial position to the PV. This might also be the most likely explanation to the much higher rate of PVI following a single cryoenergy freeze cycle if compared with the first-generation CB device. In fact, this finding is in line with the recently published article by Furnkranz *et al.*<sup>1</sup> which documented a significantly higher number of isolated PVs following a 'single shot' with the novel CB-A if compared with the older version. This observation might also question the need of a tailored approach based on PV dimensions and that the choice of balloon size should depend on pre-procedural



anatomical findings. In fact, as mentioned above, the large diameter CB-A might suffice in approaching both very small and significantly larger PV ostia due to its wider freezing area extending from the distal portion down to the equator. These considerations might lead to the tantalizing idea of abandoning LA anatomical CT or MRI imaging prior to CB-A ablation. However, achieving complete occlusion in the setting of abnormal drainage PV patterns such as additional RUPV arising from the LA roof or even common inferior trunks might prove challenging with this tool. In these particular, although significantly rarer cases, pre-procedural imaging might still prove useful in indicating these patients for a point-by-point ablation strategy with a focal tip catheter.

Finally, from an economical stand point, using only a single device, instead of an additional focal tip catheter or even of both balloon sizes in the same procedure, might also have positive and non-negligible implications in terms of procedure duration and cost-effectiveness of the ablation.

## Complications

Phrenic nerve palsy was the most common complication and occurred in 19% of individuals. When PNP occurred, PVI had been achieved in all veins. If compared with previously published data on the first-generation CB, this percentage is quite high. In fact, the new CB-A might achieve transmuralty of the thin PV antral wall in a shorter time in comparison with its predecessor and create un-necessary damage to deeper layers of extracardiac structures. Although most PNP's reverted before discharge and all in the follow-up period, this percentage remains quite high and immediate recognition is of utmost importance to avoid irreversibility. Importantly, nearly all PNP's occurred in the first 20 patients when occlusion was obtained by vigorous wedging of the CB-A in the PV ostium. In the most recent patients, this complication was dramatically reduced by achieving a more proximal seal in the right-sided veins by the means of a recently described technique.<sup>1</sup> Therefore, when using the CB-A, to minimize the occurrence of this complication, one might choose not to achieve complete isolation and rely on the distal ice-cap formation to reach isolation as recently suggested,<sup>1</sup> or alternatively to perform a more proximal occlusion in the early phases of the freeze as recently described by Casado-Arroyo *et al.*<sup>14</sup> Finally, one might rely on the technique recently published by Franceschi *et al.*<sup>15,16</sup> describing a sophisticated monitoring method that might help preempting this complication. Future studies analysing possible predictors of PNP during CB-A ablation are warranted.

Finally, we did not identify any predictors of AF recurrence following ablation. The explanation might lie in the fact that the study was clearly underpowered to identify predictors for AF recurrence and was not designed for this purpose. It should be noted that future studies with larger number of patients might be able to address these issues in individuals undergoing PVI with the CB-A.

## Limitations

Our study bares a few limitations. First, the study was a single-centre analysis conducted on a limited number of patients which might in itself create a limit in drawing substantial conclusions. Future multi-centre studies conducted on significantly larger populations of individuals are warranted to confirm our findings. Secondly, the new CB-A seems to be associated to a higher rate of oesophageal lesions.<sup>2,17</sup> We

did not perform a systematic oesophagogastroduodenoscopy to verify the presence of this complication following ablation. Therefore, the complication rate might have been underestimated. Finally, no patient was implanted with an internal loop recorder. Therefore, asymptomatic episodes might have occurred unnoticed and our success rate might have been overestimated.

## Conclusions

Cryoballoon Advance is very effective in producing PVI and affords freedom from AF at 12 months follow-up in 83% of patients affected by drug-resistant PAF following a 3-month BP. All veins could be isolated with the large 28 mm CB-A only. The most frequent complication observed was PNP which occurred in 19% of patients. Although most PNP's reverted before discharge and all in the follow-up period, this percentage remains quite high and immediate recognition is of utmost importance to avoid irreversibility.

**Conflict of interest:** G.-B.C. and C.d.A. receive compensation for teaching purposes from AF solutions Medtronic. G.-B.C. receives compensation for proctoring purposes from AF solutions, Medtronic. P.B. has received speaker fees from AF solutions.

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## IMAGES IN ELECTROPHYSIOLOGY

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### Successful transbaffle catheter ablation of pulmonary vein tachycardia

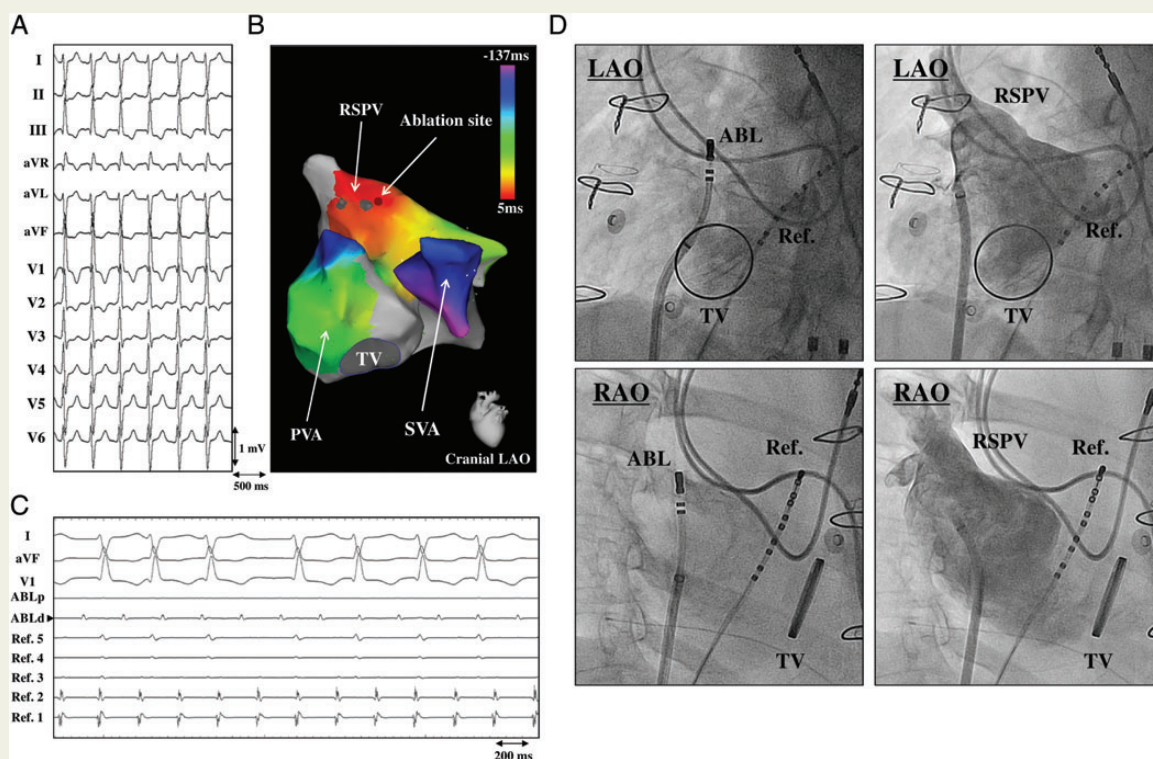
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A 46-year-old woman with a history of transposition of the great arteries, Mustard operation, and tricuspid valve (TV) replacement underwent catheter ablation of atrial tachycardia (AT) (Panel A). No early activation was found in the systemic venous atrium (SVA). Transbaffle puncture was performed with the guidance of fluoroscopy and venogram to map in the pulmonary venous atrium (PVA), revealing a centrifugal activation pattern from the right superior pulmonary vein (RSPV) ostium (Panel B). A radiofrequency application at the earliest activation site (Panels C and D) eliminated the AT. This case illustrated successful transbaffle catheter ablation of a non-reentrant pulmonary vein tachycardia after a Mustard operation.



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